UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re EDAP TMS S.A. SECURITIES LITIGATION

14 Civ. 6069 (LGS)

OPINION AND ORDER

LORNA G. SCHOFIELD, District Judge:

Plaintiffs bring this putative class action on behalf of all persons or entities that purchased or otherwise acquired American Depository Receipts ("ADRs") of EDAP TMS S.A ("EDAP" or the "Company") on the NASDAQ Exchange, from February 1, 2013, through and including July 30, 2014 (the "Class Period"), seeking remedies under the Securities Exchange Act of 1934. Plaintiffs allege that Defendants EDAP and its CEO Marc Oczachowski made material misrepresentations and omissions, upon which Plaintiffs relied in purchasing EDAP ADRs. Defendants move to dismiss the First Amended Complaint (the "Complaint") pursuant to Federal Rules of Civil Procedure 12(b)(6), 8 and 9(b) and the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(b)(3)(a). Because the Complaint fails to state a claim for relief under § 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder, the motion is granted in its entirety.

BACKGROUND

Unless otherwise noted, the facts below are taken from the Complaint, documents integral to the Complaint and documents of which the Court may take judicial notice. They are assumed to be true for the purposes of this motion. *See Press v. Quick & Reilly, Inc.*, 218 F.3d 121, 129 (2d Cir. 2000) ("[I]t is highly impractical . . . to preclude a district court from

considering [documents referenced in a complaint and filed with the SEC] when faced with a motion to dismiss a securities action based on allegations of material misrepresentations or omissions." (quoting *Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991)).

I. THE PARTIES

EDAP -- incorporated and headquartered in France -- is a medical equipment company that develops ultrasound solutions for urology, tumor removal, prostate cancer and other infectious diseases. Oczachowski has served as EDAP's CEO at all times relevant to this action. EDAP ADRs are listed on the NASDAQ. According to the Complaint, one of EDAP's most important products in development is Ablatherm, which treats organ-confined prostate cancer by applying high-intensity focused ultrasound ("HIFU") to the prostate gland. As there are no other HIFU devices currently on the market, most patients with prostate cancer are treated through prostatectomy, radiation or regular monitoring. Ablatherm is approved for use as a treatment for prostate cancer in Europe, but has not been approved by the FDA for use in the United States.

Plaintiffs bring this suit as a putative class action on behalf of all individuals or entities who purchased or otherwise acquired EDAP ADRs on the NASDAQ during the Class Period.

II. THE FDA REVIEW PROCESS

FDA approval is required before pharmaceuticals and devices may be marketed in the United States. The FDA requires rigorous testing to ensure that a drug or device is safe and effective for its intended use. Before considering approval of a device, the FDA requires a sponsor to submit a Premarket Approval ("PMA") application, which contains data from clinical trials, preclinical studies and manufacturing information that supports the product's safety and efficacy. 21 U.S.C. § 360e.

The FDA may choose to file a PMA application, "mean[ing] that FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review." 21 C.F.R. § 814.42(a). The FDA's filing of an application marks the beginning of the PMA application's substantive review. 21 C.F.R. § 814.42(b). The FDA may instead, however, refuse to file a PMA application if, inter alia, the application does not contain all the information required by the Food, Drug and Cosmetic Act and 21 C.F.R. § 814.20. 21 C.F.R. § 814.42(e) (citing 21 U.S.C. § 360e and 21 C.F.R. § 814.20).

In interpreting the Food, Drug and Cosmetic Act, the FDA has maintained that "Congress generally intended to require at least two adequate and well-controlled studies, each convincing on its own, to establish effectiveness." Food and Drug Admin., Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (1998), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm078749.pdf (last visited Sept. 11, 2015). However, despite this interpretation, the "FDA has been flexible within the limits imposed by the congressional scheme" and has relied on other forms of data to determine the effectiveness of a product. For example, the "effectiveness of a new [product] may be extrapolated entirely from existing efficacy studies."

During the FDA's substantive review of the application, the FDA may choose to refer the application to an advisory panel. 21 C.F.R. § 814.44(a). After reviewing the application, the advisory panel holds a public meeting to review the PMA application and then submits a report to the FDA, stating the panel's recommendation whether to approve the application and detailing the reasons for the recommendation. 21 C.F.R. § 814.44(b). The panel's recommendation is not binding, but the FDA generally considers the panel's report and recommendation when making its final determination on a PMA application. *See* 21 C.F.R. § 814.44(c).

Throughout the review process, the FDA may communicate with the PMA applicant and, inter alia, "request the applicant to amend a PMA . . . with any information regarding the device that is necessary for FDA or the appropriate advisory committee to complete the review of the PMA." 21 C.F.R. § 814.37(b)(1).

Within 100 days after the FDA's receipt of the application, the applicant may request a "Day-100 Meeting" to discuss the application's review status. 21 U.S.C. § 360e(d)(3). Prior to the meeting, the FDA must "provide to the applicant a description of any deficiencies in the application that, at that point, have been identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies." 21 U.S.C. § 360e(d)(3)(A)(ii).

If the FDA ultimately chooses not to approve the PMA application, it issues a "not approvable letter" to the applicant if it determines, inter alia, that "there is a lack of a showing of reasonable assurance that [the] device is safe . . . [or] effective." 21 U.S.C. § 360e(d)(2); 21 C.F.R. § 814.45.

III. FDA REVIEW OF ABLATHERM

In 2007, EDAP began a study in the United States to compare Ablatherm to cryotherapy as a treatment for prostate cancer (the "U.S. Clinical Trial"). EDAP faced difficulties finding a sufficient number of patients to participate in the cryotherapy group, and in 2009, EDAP met with the FDA "to propose alternatives to the approved protocol and its prospective comparative study."

In December 2009, the FDA convened a general meeting of the Gastroenterology and Urology Devices Panel. According to the Complaint, the panel "made clear that any application

for FDA approval of a treatment for prostate cancer should (i) be based on prospective data for endpoint evaluation . . . and (ii) include follow-up data for a minimum five-year period."

In January 2010, EDAP again met with the FDA to discuss "options and alternatives" for moving forward with the U.S. Clinical Trial. According to the Complaint, the FDA "confirmed the Panel's recommendation for a prospective study and reiterated the Panel's concerns regarding the concept of patient randomization and the follow-up period." In April 2010, EDAP discontinued enrollment of patients in the cryotherapy group and informed the FDA of its action. In June 2010, EDAP completed treating 134 patients treated with Ablatherm and followed up with these patients for two years afterward.

On January 31, 2013, EDAP submitted to the FDA its PMA application for Ablatherm. Despite the limited enrollment in the U.S. Clinical Trial, EDAP included in its application (1) data from the U.S. Clinical Trial as well as (2) data from a worldwide database of treatment information and follow-up data from HIFU patients. On March 26, 2013, the FDA notified EDAP that it had accepted its PMA application for filing. In around May 2013, the FDA issued a "Major Deficiency Letter" to EDAP, stating that (1) the application lacked sufficient evidence to assess effectiveness, in part due to EDAP's use of an "unvalidated endpoint" and (2) the FDA had "significant concerns" about the comparability of the safety profiles of HIFU and alternative treatments. In particular, EDAP had selected "long term freedom from metastasis following treatment" as its studies' primary objective, which the Complaint alleges was "an incorrect primary endpoint, as the FDA pointed out in its Major Deficiency Letter." According to the Complaint, the FDA believed "overall survival" should have been selected as the primary endpoint. The Complaint alleges that the FDA made it "abundantly clear" that it considered EDAP's chosen endpoint as a "surrogate for the gold standard endpoint of overall survival."

As the Major Deficiency Letter is not publicly available, Plaintiffs admit that they have never seen the letter, and the Complaint draws upon the transcript of a subsequent panel meeting to summarize the contents of the letter. It is unclear when the FDA sent this letter to EDAP; the Complaint estimates that EDAP received the letter no later than early May 2013, as EDAP announced on May 16, 2013, that it had requested its Day-100 Meeting presumably to discuss issues raised in the letter. The Day-100 Meeting was held in early June 2013.

After the Day-100 Meeting, EDAP submitted an amendment to its PMA application that (1) compared European data on eight-year metastasis-free survival among Ablatherm patients with American data from a "low risk subgroup of patients" treated with radical prostatectomy and (2) added safety data from, inter alia, a meta-analysis of HIFU and cryotherapy literature.

The FDA scheduled an advisory panel hearing on EDAP's PMA application for July 30, 2014. In advance of the meeting, the FDA published a Briefing Document that flagged several issues concerning EDAP's application, including concerns about (1) the clinical meaningfulness of the comparison between European and American patients submitted in the PMA amendment, (2) limitations in making cross-study comparisons and (3) the safety profile of Ablatherm compared to other treatment procedures. Concerning the PMA application's primary endpoint, the Briefing Document stated, "Even though metastasis-free survival" -- the endpoint EDAP selected -- "is a potentially useful endpoint in prostate cancer, the use of this endpoint is challenging due to the low event rate in the low risk group."

At the July 30 hearing, the panel voted against recommending Ablatherm's approval. On the question of safety, three panel members voted yes, five no and one abstained. On the question of efficacy, all nine members voted no. On the question of the risk-benefit ratio for treating prostate cancer with Ablatherm, eight voted no and one member abstained. The

Company issued a press release reporting the vote after the close of trading on July 30, 2014. The price of EDAP ADRs dropped almost 44 percent the following day, closing at $1.92. On November 6, 2014, the Company announced that it had received a letter from the FDA "stating that the Ablatherm PMA was not approvable in its current form."

Plaintiffs filed this action on August 4, 2014 and filed the First Amended Complaint -- currently the operative complaint -- on December 22, 2014. (Dkt. No. 39).

IV. ALLEGED MATERIAL MISREPRESENTATIONS AND OMISSIONS

The Complaint identifies alleged misrepresentations and omissions that fall into three categories. The first category consists of optimistic updates and comments about developments in the FDA review process ("FDA Review Statements"). The FDA Review Statements include the following:

- In a February 1, 2013, press release, Oczachowski stated, "The PMA submission to the FDA represents a significant milestone in the U.S. regulatory process for Ablatherm-HIFU."

- In a March 28, 2013, press release, Oczachowski stated, "Receiving FDA acceptance for our PMA in less than two months is both very timely and a major milestone." An April 2, 2013, press release and a May 21, 2013, letter to shareholders used similar language.

- In a April 24, 2014, earnings conference call, Oczachowski stated that "EDAP has achieved several key milestones in 2013 in advancing the PMA application for Ablatherm HIFU device through the FDA review process," including the FDA's filing acceptance, and that "[w]e are very pleased and extremely excited that we were able to advance this process significantly throughout 2013 and during the first quarter of 2014."

- In a May 16, 2013, press release, Oczachowski stated, "The FDA process for our Ablatherm-HIFU is on track as we submitted our Pre-Market Approval (PMA) application that was reviewed and approved for filing in late March."

- During a November 21, 2013, earnings conference call, Oczachowski said, "Today we believe we are moving through the approval process in a timely manner." In a press release issued the same day, Oczachowski remarked that EDAP's completion of its response to FDA questions "is another significant milestone within the FDA approval process" and that "[w]e do not believe there will be any further questions related to the

filing or additional requests from the FDA prior to the panel meeting." An April 3, 2014, press release contained similar language.

- In a May 22, 2014, press release -- announcing the confirmation of the panel meeting concerning Ablatherm -- Oczachowski stated, "Confirmation of this important milestone is great news for the Company and its PMA application. . . . We are very excited to now have a much clearer path toward FDA approval." Similarly, in a May 28, 2014, press release -- commenting on confirmed dates for the panel meeting, an FDA inspection of EDAP's factory and an FDA audit of the clinical study investigation sites -- Oczachowski stated, "Having dates confirmed for these additional milestones is further great news for EDAP, as it demonstrates how quickly the FDA process is moving for our Ablatherm-HIFU PMA application. We are very enthusiastic to see the progression of events since our last complete submission in March of this year and consider this to be a very exciting time in the Company's history."

The Complaint alleges that these statements were misrepresentations because they mischaracterized developments in the review process as "milestones" and "progress" that, in reality, "signified nothing about the PMA's chances of receiving FDA approval," and described the review process as "on track."

The second category consists of statements concerning Ablatherm studies, particularly the sufficiency of the data demonstrating efficacy and Ablatherm's safety profile compared to other modes of treatment ("Data Statements"). These Data Statements include:

- In a February 8, 2013, press release concerning the U.S. Clinical Trial, the Company stated, "The study solidifies the fact that HIFU is a safe and effective therapeutic option for patients with localized prostate cancer of low and intermediate risk profile. The morbidity experienced by patients was reasonable and, specifically, the rate of serious side effects such as recto-urethral fistulae is very low."

- During an August 28, 2013, call, Oczachowski stated that three major clinical papers' acceptance for publication on Ablatherm-HIFU is "quite unique as most of the other treatment modalities do not have such papers covering these many patients with such long-term follow-up. He further said, "This will certainly contribute to our ability to move forward into different regulatory program and pass around the world and in the U.S." A June 10, 2014, letter to shareholders contained similar language about the papers and stated, "We believe this data demonstrates the excellent efficacy results of Ablatherm HIFU in the treatment of prostate cancer with very high cancer-free survival and metastasis-free rates."

- During a November 21, 2013, earnings conference call, Oczachowski was asked whether any of the FDA's questions "have to do with the efficacy of Ablatherm or the HIFU product." Oczachowski responded, "No. I would say it is more clarification questions. You need to clarify points, and you have to get them to kind of evaluate and integrate the file. So, it is more on methods and it is more -- it is quite variable and it is quite mixed as well."

- In a March 11, 2014, interview with the Wall Street Transcript, Oczachowski commented on Ablatherm's "low morbidity profile and retreatment capability." He further stated, "HIFU brings about the same efficacy as a radical treatment, like surgery or radiation, but the morbidity profile, the side effects are much lower . . . . [I]t brings a very high level of efficacy based on publications of more than 10 years of data, and it has a very low morbidity profile -- so it preserves the quality of life of the patient." He made similar comments in an April 24, 2014, earnings conference call, specifically that, "In aggregate, these results were first very consistent and stable from one paper to the other, and second, they showed a very high efficacy level with 98% of cancer specific survivor rate and 95% of metastasis-free rate at 10 years following treatment with Ablatherm HIFU."

The Complaint alleges that these statements were false or misleading because (1) EDAP did not have sufficient data demonstrating HIFU's safety or efficacy and in fact relied on faulty statistical methods and (2) morbidity and adverse effects -- including erectile dysfunction and urinary incontinence -- suffered by patients treated with HIFU were not "reasonable."

Rather than express statements or representations, the third category consists of omissions concerning the FDA's Major Deficiency Letter ("Deficiency Letter Omissions"). Specifically, the Complaint alleges that statements made after May 16, 2013 -- whether FDA Review Statements, Data Statements or otherwise -- were false or misleading because they did not mention the Major Deficiency Letter, which alerted EDAP to "significant deficiencies" in and casted "considerable doubt on the viability of its PMA application." According to the Complaint, these deficiencies included "the Company's failure to use the correct primary endpoint for effectiveness and its reliance on safety data that had serious comparability limitations," the use of "faulty statistical methods" and the presentation of "incomplete data."

V. SCIENTER ALLEGATIONS

In addition to the allegations described above, the Complaint avers that Defendants consider Ablatherm a "core product" whose FDA approval is "key to the Company's financial success" and "the Company's ability to gain general acceptance" around the world. The Complaint alleges that, due to Ablatherm's importance to EDAP, Defendants were aware of material facts about the FDA review process, including the Major Deficiency Letter. Furthermore, the Complaint alleges that Defendants "were motivated to conceal the true adverse facts concerning their PMA because they needed to raise additional funds from investors to continue funding the entry of Ablatherm into the U.S. market."

VI. CAUTIONARY LANGUAGE

EDAP's 20-F filings with the Securities and Exchange Commission and its prospectus contained a long "Cautionary Statement on Forward-Looking Information." In relevant part, the statement read, "Actual events or results may differ materially from those expressed or implied in [] forward-looking statements as a result of various factors that may be beyond our control." The statement listed a number of factors including, "the clinical and regulatory status of our HIFU devices"; "the uncertainty of market acceptance for our HIFU devices" and "the uncertainty in the U.S. FDA approval process and changes in FDA recommendations and guidance." EDAP's prospectus contained similar language. EDAP's press releases referred to this statement and noted, "Ablatherm-HIFU treatment is in clinical trials, but [is] not FDA-approved or marketed in the United States." At the beginning of EDAP's earnings conference calls, participants were reminded that management's remarks "may contain forward-looking statements" that are "subject to a number of uncertainties and risks that could cause actual results

to differ," including the factors described in the Company's filings with the Securities and Exchange Commission.

STANDARD

Pursuant to Federal Rule of Civil Procedure 12(b)(6), "[t]o survive a motion to dismiss, a complaint must plead 'enough facts to state a claim to relief that is plausible on its face.'" *ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009) (quoting *Ruotolo v. City of New York*, 514 F.3d 184, 188 (2d Cir. 2008)). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

To allege a violation of § 10(b) and Rule 10b-5, a plaintiff must plead the elements of the claim: "(1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance . . .; (5) economic loss; and (6) loss causation[.]" *Kleinman v. Elan Corp.*, 706 F.3d 145, 152 (2d Cir. 2013) (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005)).

"Any complaint alleging securities fraud must satisfy the heightened pleading requirements of the PSLRA and Fed. R. Civ. P. 9(b) by stating with particularity the circumstances constituting fraud." *ECA, Local 134*, 553 F.3d at 196. "A securities fraud complaint based on misstatements must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007). Allegations of fraud may be "too speculative even on a

motion to dismiss," particularly when premised on "distorted inferences and speculations." *Id.* at 104 (internal quotation omitted).

"The PSLRA expanded on the Rule 9(b) standard, requiring that 'securities fraud complaints specify each misleading statement; that they set forth the facts on which [a] belief that a statement is misleading was formed; and that they state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Anschutz Corp. v. Merrill Lynch & Co.*, 690 F.3d 98, 108 (2d Cir. 2012) (quoting *Dura*, 544 U.S. at 345). "To prove liability against a corporation, of course, a plaintiff must prove that an agent of the corporation committed a culpable act with the requisite scienter, and that the act (and accompanying mental state) are attributable to the corporation." *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 195 (2d Cir. 2008).

DISCUSSION

I. MATERIAL MISREPRESENTATIONS AND OMISSIONS

A. Applicable Law

A statement or omission is materially misleading when there is "a substantial likelihood that the disclosure of the omitted [or corrected] fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available" to the market. *Matrixx Initiatives, Inc. v. Sircusano*, 131 S. Ct. 1309, 1318 (2011) (internal quotation marks omitted). "[It] bears emphasis that § 10(b) and Rule 10b-5 do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary to make . . . statements made, in the light of the circumstances under which they were made, not misleading." *Id.* at 1321 (internal quotations omitted). The "total mix" standard "does not mean that pharmaceutical manufacturers must disclose all reports of adverse

events." *Id.* "The question remains whether a *reasonable* investor would have viewed the nondisclosed information as having *significantly* altered the total mix of information made available." *Id*. (internal quotations omitted).

The Second Circuit has "identified several important limitations on the scope of liability for securities fraud." *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000). First, the Second Circuit has rejected claims that allege "fraud by hindsight." *See id.* (holding that "allegations that defendants should have anticipated future events and made certain disclosures earlier than they actually did do not suffice to make out a claim of securities fraud") (citations omitted). That is, "misguided optimism" or statements that later turned out to be untrue, are not actionable. *Shields v. Citytrust Bancorp., Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994); *accord Stevelman v. Alias Research Inc.*, 174 F.3d 79, 85 (2d Cir 1999). "Corporate officials need not be clairvoyant; they are only responsible for revealing those material facts reasonably available to them." *Novak*, 216 F.3d at 309.

Second, "expressions of puffery and corporate optimism do not give rise to securities violations." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004). "[A]s long as the public statements are consistent with reasonably available data, corporate officials need not present an overly gloomy or cautious picture of current performance and future prospects." *Novak*, 216 F.3d at 309 (citation omitted). In general, "subjective statements of opinion are generally not actionable as fraud." *In re Sanofi Sec. Litig.*, No. 13 Civ. 8806, 2015 WL 365702, at *12 (S.D.N.Y. Jan. 28, 2015). "Subjective statements can be actionable only if the 'defendant's opinions were both false and not honestly believed when they were made.'" *Kleinman*, 706 F.3d at 153.

The PSLRA contains a safe-harbor provision that precludes securities fraud actions based on forward-looking statements that are identified as such and "accompanied by meaningful cautionary statements." 15 U.S.C. § 78u-5(c)(1)(A)(i). Under the "bespeaks caution" doctrine, "alleged misrepresentations . . . are [deemed] immaterial as a matter of law [if] it cannot be said that any reasonable investor could consider them important in light of adequate cautionary language." *Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 357 (2d Cir. 2002); *accord Iowa Pub. Employees' Ret. Sys. v. MF Global, Ltd.*, 620 F.3d 137, 144 n.14 (2d Cir. 2010) ("To the extent that puffery suggests a rosy future, the principle underlying bespeaks caution applies."). To determine whether cautionary language is meaningful, courts must first "identify the allegedly undisclosed risk" and then "read the allegedly fraudulent materials -- including the cautionary language -- to determine if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist." *Halperin*, 295 F.3d at 359; *accord ECA, Local 134*, 553 F.3d at 206 (2d Cir. 2009) (holding that statements that "did not, and could not, amount to a guarantee that its choices would prevent failures in its risk management practices" were "precisely the type of 'puffery' that this and other circuits have consistently held to be inactionable" (internal quotation marks omitted)).

Third, "[a]ccurate statements about past performance are self evidently not actionable under the securities laws." *Nadoff v. Duane Reade, Inc.*, 107 F. App'x 250, 252 (2d Cir. 2004) (summary order). This holds true even if projections for the future appear less favorable than past performance. *See In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 401 n.3 (6th Cir. 1997) ("[D]isclosure of accurate historical data does not become misleading even if less favorable results might be predictable by the company in the future."); *accord In re Nokia Corp. Sec. Litig.*, 423 F. Supp. 2d 364, 395 (S.D.N.Y. 2006) ("Defendants may not be held liable under the

securities laws for accurate reports of past successes, even if present circumstances are less rosy.") (quotation omitted).

B. Application

1. FDA Review Statements

Many of the alleged misrepresentations constitute updates concerning the latest developments in the PMA review process. The Complaint cites a number of statements in which Defendants (1) characterize various steps of the PMA review process as "milestones"; (2) state that the process was "on track" and making continued "progress"; (3) declared their belief that they were "moving through the approval process in a timely manner"; and (4) expressed their excitement about "great news" and having "a much clearer path toward FDA approval." For the following reasons, these statements are not actionable.

First, as all of these statements comment on the evolving status of the Company's PMA application, they are not actionable to the extent that they merely recite historical fact. *See Fort Worth Employers' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 230 (S.D.N.Y. 2009) (holding statements about FDA's acceptance of application for review were inactionable as recitation of fact) (citing *In re Int'l Bus. Machs. Corporate Sec. Litig.*, 163 F.3d 102, 108 (2d Cir. 1998)). Indeed, the Complaint does not allege the facts underlying these statements to be false. *See id.*

Second, insofar as these statements place a positive spin on developments in the PMA process, they constitute inactionable puffery and corporate optimism. *ECA, Local 134*, 553 F.3d at 206; *In re S1 Corp. Sec. Litig.*, 173 F. Supp. 2d 1334, 1356 (N.D. Ga. 2001) (finding that company's assertions that it had achieved financial 'growth milestones' "constitute vague puffing and immaterial corporate optimism"). At no point does the Complaint allege that

Defendants guaranteed or even predicted FDA approval; at most, Defendants' characterization of the process in these statements -- including use of the terms "timely" and "on track" -- "reflect[] only the slightest degree of optimism." *Fort Worth Employers' Ret. Fund*, 615 F. Supp. 2d at 230.

Third, to the extent that they are forward-looking, these statements fall within the PSLRA's safe harbor provision and are inactionable. The Company consistently gave warnings that the FDA might not approve the Company's product, and no reasonable investor could have believed that there was no risk in this regard. *See Halperin*, 293 F.3d at 359. Although Plaintiffs argue that Defendants failed to provide anything more than boilerplate warnings insufficient to warrant safe-harbor protection, Defendants adequately provided investors with cautionary language that "warned of" and "directly related" to the risk of the FDA's rejection of EDAP's PMA application. Defendants repeatedly cautioned that factors such as "the clinical and regulatory status of our HIFU devices," "the uncertainty of market acceptance for our HIFU devices" and "the uncertainty in the U.S. FDA approval process" "could affect future results." They also made clear that "Ablatherm-HIFU treatment is in clinical trials, but [is] not FDA-approved or marketed in the United States." Defendants therefore adequately disclosed the possibility of a risk that materialized when the FDA denied approval of EDAP's PMA application.

These statements therefore do not give rise to a viable securities fraud claim.

2. Data Statements

The Data Statements are also inactionable, as they constitute expressions of opinion and allegations of "fraud by hindsight."

First, notwithstanding Plaintiffs' characterization of the data supporting EDAP's application as "utterly deficient," the Data Statements -- touting Ablatherm as "safe and effective" and boasting of "excellent efficacy" and "low morbidity" -- are inactionable expressions of opinion. *See Sanofi*, 2015 WL 365702, at *12. "Plaintiffs cannot premise a fraud claim upon a mere disagreement with how defendants chose to interpret the results of the clinical trial." *In re MELA Sciences, Inc. Sec. Litig.*, No. 10 Civ. 8774, 2012 WL 4466604, at *13 (S.D.N.Y. Sept. 19, 2012) (denying motion to amend complaint in securities fraud action, where defendant made statements that clinical trial achieved "positive top line results" and plaintiff's alleged failure to disclose "unsound statistical analysis" and other design flaws in clinical trial). Furthermore, the European studies referenced in the Complaint support Defendants' positive interpretation of the data, precluding a finding that Defendants' opinions were "false" or "not honestly believed when they were made."

Second, Plaintiffs' allegations concerning these statements plead nothing more than fraud by hindsight. Although the FDA had identified deficiencies in EDAP's data during the review process, the Complaint contains insufficient allegations to "infer that it was a 'foregone conclusion' that . . . adverse consequences would ensue." *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 53 (2d Cir. 1995) (affirming dismissal of securities fraud claims based on company's delay in disclosing deficiencies identified in FDA inspections during pendency of drug applications).

Third, although the Complaint alleges that Defendants did not disclose the high incidence of adverse events on certain occasions, the Complaint fails plausibly to allege that such data were never disclosed to the public. Plaintiffs overlook that the law looks to the "total mix" of information available to investors and that this mix includes the published studies that the Complaint cites. These studies document the side effects and morbidity that supposedly

remained undisclosed to Plaintiffs until the FDA hearing on July 30. As in *Sanofi*, Plaintiffs here do "not allege that these publicly available reports omitted any adverse events that had been observed, or that these reports were otherwise incomplete." 2015 WL 365702 at *31. "Defendants were not obliged to reproduce a comprehensive enumeration of adverse events every time they mentioned [Ablatherm]'s safety profile." *Id.* Indeed, even the portion of the FDA Briefing Document that the Complaint quotes is more tentative concerning morbidity than Plaintiffs suggest. The quoted portion states, "Several of the separately-reported adverse event categories are related, and *may* be more clinically meaningful for interpretation when combined . . . ." Compl. at ¶ 6 (emphasis added).

Finally, Oczachowski's response to a question concerning the FDA's inquiries is worth closer scrutiny. Asked whether any of the FDA's questions "have to do with the efficacy of Ablatherm or the HIFU product," Oczachowski responded, "No. I would say it is more clarification questions. You need to clarify points, and you have to get them to kind of evaluate and integrate the file. So, it is more on methods and it is more -- it is quite variable and it is quite mixed as well." Defendants persuasively argue that Oczachowski responded accurately; that is, even based on Plaintiffs' characterization of the Deficiency Letter, the FDA questioned the sufficiency of evidence concerning efficacy rather than Ablatherm's efficacy itself. Plaintiffs dismiss the distinction between efficacy and sufficiency of the evidence to assess efficacy as "wordplay." Plaintiffs argue, "The FDA cannot assess whether Ablatherm is efficacious if the Company does not give it sufficient evidence to assess it." Plaintiffs' argument, however, is undermined by the FDA Advisory Panel's recognition of this very distinction. One member of the panel -- who ultimately voted against approval -- commented, "It's not that I don't believe the therapy works or doesn't work. It may very well work; I just don't know because the data

that's being used is indeterminate." The Complaint's characterization of the "non-approvable letter" sent by the FDA to Defendants supports this distinction; according to the Complaint, the letter "stat[ed] that the Ablatherm application was *not approvable in its current form*, and would require *additional data submissions* to warrant further review." Compl. at ¶ 11 (emphases added).

Accordingly, Plaintiffs' claim concerning these statements is dismissed.

3. Deficiency Letter Omissions

Although this category overlaps with the other two to some extent, the Deficiency Letter Omissions are analyzed separately, as they seem to form Plaintiffs' principal theory of liability. The allegations premised on these Omissions are inactionable as well.

Numerous courts across the country have found that defendants in securities fraud actions had no obligation to disclose the substance of FDA inquiries made during the pendency of a drug or device application. *See Sanofi*, 2015 WL 365702, at *19 ("The law did not impose an affirmative duty to disclose the FDA's interim feedback just because it would be of interest to investors.") (citing *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002)); *In re Alkermes Sec. Litig.*, No. Civ. A. 03-12091, 2005 WL 2848341, at *16 (D. Mass. Oct. 6, 2005) ("The Defendants had no duty to disclose that the FDA had requested additional studies because they had never guaranteed FDA approval."); *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("Mere questioning by the FDA imposed no duty upon Defendants either to trim back their opinions as to the efficacy of the drug or to report to the public the FDA staffers' questions as they arose. . . . Defendants, as a general proposition, had no duty to report its ongoing discussions with FDA during the review process."); *cf. Padnes v. Scios Nova Inc.*, No. C 95-1693, 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996) (holding that company, in

summarizing results of study, were not obligated to "disclose[] details of the study which [Plaintiffs] characterize[d] as design defects"). As in these cases, Defendants had no duty to disclose the content of the Major Deficiency Letter or "trim back their opinions as to the efficacy of the drug." *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. at 966.

Furthermore, the Complaint overstates the gravity of the FDA's concerns about EDAP's selected primary endpoint. Indeed, language from the Briefing Document that the Complaint quotes makes clear that EDAP's use of metastasis-free survival as a primary endpoint did not doom EDAP's PMA application. The Briefing Document stated that metastasis-free survival is "a potentially useful endpoint," although "the use of this endpoint is challenging." Furthermore, a presenter at the Panel Meeting commented, "[M]etastasis-free survival is a potentially acceptable endpoint . . . and has been used by the FDA as a basis for approval of other treatments for other malignancies." In other words, although metastasis-free survival may not be the ideal endpoint, the FDA did not consider it to be completely unacceptable.

Likewise, the Complaint overstates the FDA's concerns about data comparing Ablatherm's safety to alternative treatments. As mentioned above, language from the Briefing Document quoted by the Complaint is -- on its face -- not as damning as Plaintiffs suggest; that language stated only that several adverse event categories reported as separate by EDAP "*may* be more clinically meaningful for interpretation when combined." Compl. at ¶ 6 (emphasis added). In addition, a presenter at the Panel Meeting remarked that Ablatherm's "high rates of erectile dysfunction" "are not dissimilar to that reported following surgery or radiation."

Plaintiffs' arguments to the contrary are unavailing. Plaintiffs' reliance on this Court's opinion in *In re Delcath Systems, Inc. Securities Litigation*, 36 F. Supp. 3d 320 (S.D.N.Y. 2014), is misplaced. There, Defendants disclosed certain data points that reflected positively on its

product but failed to disclose comparative data that might reflect poorly on its product. *Id.* at 331-32; *see also In re Intercept Pharm., Inc. Sec. Litig.*, No. 14 Civ. 1123, 2015 WL 915271, at *7 (S.D.N.Y. Mar. 4, 2015) (finding sufficient inference of scienter where defendant "chose . . . only to report the positive development, engaging in the sort of selective disclosure that creates a real possibility of misleading investors"); *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 346 (E.D. Pa. 2014) (defendants transmitted part of FDA guidance but omitted another part of guidance giving defendants "cautionary warning" about submitted data's sufficiency for approval). The Complaint does not allege any analogous form of selective disclosure here.

The remaining decisions that Plaintiffs cite -- none from this Circuit -- are likewise inapposite. *See, e.g., In re Viropharma Inc. Securities Litigation*, 21 F. Supp. 3d 458, 465 (E.D. Pa. 2014) (defendants submitted application to FDA without components required by statute); *In re Transkaryotic Therapies, Inc. Sec. Litig.*, 319 F. Supp. 2d 152, 156 (D. Mass. 2004) (defendants made public statements that FDA merely had asked for "further explanation in several areas and additional data," where FDA's letter made clear new trials were necessary and submission of additional data from extant studies would be "unable to address this deficiency"); *In re Amylin Pharm., Inc. Sec. Litig.n*, No. 01 Civ. 1455, 2003 WL 21500525, *1, 2, 8 (S.D. Cal. May 1, 2003) (defendants' trials were unable to achieve statistical significance without modification and defendants made public statements that, in their opinion, "the trial results met the requirements for FDA approval" (emphasis omitted)).

Accordingly, the Deficiency Letter Omissions do not support a claim for securities fraud.

II. SCIENTER

The Complaint also fails to adequately plead scienter, providing an independent basis for dismissing this action.

The PSLRA requires a plaintiff to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). "This standard requires courts take into account 'plausible opposing inferences.'" *Matrixx*, 131 S. Ct. at 1324 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007)). A complaint sufficiently pleads scienter "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. In this Circuit, a plaintiff may satisfy the scienter requirement by alleging facts that show either that "the defendants had both motive and opportunity to commit the fraud" or that offer "strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI*, 493 F.3d at 99.

The Complaint fails to allege scienter under a theory of motive and opportunity, because there are no allegations that Defendants possessed unique motives not shared by all insiders of corporations. "[M]otives possessed by virtually all corporate insiders, including . . . the appearance of corporate profitability, or of the success of an investment, . . . the desire to maintain a high stock price in order to increase executive compensation, . . . or prolong the benefits of holding corporate office" are not sufficient to support an inference of scienter. *Novak*, 216 F.3d at 307 (Internal citations omitted). Instead, plaintiffs must allege that "defendants benefitted in some concrete and personal way from the purported fraud." *Id*. at 307-08. The Complaint alleges no such concrete and personal benefit.

Nor does the Complaint sufficiently allege that Defendants consciously or recklessly made false or misleading misrepresentations or omissions. "At least four circumstances may give rise to a strong inference of scienter . . . ." *ECA, Local 134*, 553 F.3d at 199. The one that is relevant here is where a complaint sufficiently alleges that the defendants "knew facts or had

access to information suggesting that their public statements were not accurate." *Id.* (internal quotation omitted). Plaintiffs can plead conscious misbehavior or recklessness by "alleg[ing] defendants' knowledge of facts or access to information contradicting their public statements." *Novak*, 216 F.3d at 308.

Taken together, the Complaint's allegations do not support a cogent inference of scienter that is "at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. Despite Plaintiffs' arguments, a more compelling inference to the contrary exists -- that "the company could have known of problems in the testing procedures, planned to remedy those deficiencies, and still thought it would achieve FDA approval." *In re Syntext Corp. Securities Litig.*, 95 F.3d 922, 930 (9th Cir. 1996); *accord id.* ("Any alleged deficiencies in the testing procedures do not indicate that [the Company's] prediction of an FDA approval date was false when made."); *MELA Sciences*, 2012 WL 4466604, at *13 (reasoning that, despite defendants' receipt of letter from FDA detailing deficiencies in clinical trial, that "[t]here is no basis to conclude defendants characterized the results of the clinical trial in a manner inconsistent with what they believed to be the truth.").

Indeed, the Complaint's allegations -- that Defendants began the U.S. Clinical Trial in 2007 and consulted with the FDA on numerous occasions about difficulties in conducting a clinical trial -- support an inference that Defendants worked diligently to comply with FDA requirements and honestly believed that their diligence would lead to approval of their PMA application. Commentary from the advisory panel at the July 30, 2014, hearing supports this inference. One panel member remarked, "I think they did this very rigorously, and very honestly, but I do not think it's adequate." At another point, a panel member noted, "I am full of admiration for what they did." The panel further discussed the challenge of designing rigorous

clinical trials for prostate cancer treatments. Thus, a "non-culpable explanation" for the facts alleged in the Complaint is not only "as compelling" as the inference Plaintiffs propose, but is more plausible than the narrative Plaintiffs depict.

Therefore, the Complaint's failure to adequately plead scienter provides an independent basis for dismissal.

III. SECTION 20(a) CLAIM

To state a claim for control person liability under § 20(a) of the Securities Exchange Act, a plaintiff must show "(1) a primary violation by a controlled person; (2) control of the primary violator by the defendant; and (3) that the controlling person was in some meaningful sense a culpable participant in the primary violation." *Boguslavsky v. Kaplan*, 159 F.3d 715, 720 (2d Cir. 1998) (internal quotations omitted). As the primary claim here is dismissed, the § 20(a) claim must be dismissed as well. *See In re Agnico-Eagle Mines Ltd. Sec. Litig.*, No. 11 Civ. 7968, 2013 WL 144041, at *21 (S.D.N.Y. Jan. 14, 2013).

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is GRANTED in its entirety. The Clerk of Court is respectfully directed to close the motion at Docket No. 40.

SO ORDERED.

Dated: September 14, 2015
New York, New York

LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE